

OTA-24-008: Systems Biology Data Platform Leveraging the Accelerating Medicines Partnership (OT2)

March 18, 2024

An NIH Common Fund Venture Program Initiative



National Institutes of Health

Office of Strategic Coordination – The Common Fund

Agenda

- Overview of the Common Fund and the Venture Program
- Overview of the SysBio Research Opportunity Announcement (ROA)
- Questions & Answers

Overview of the Common Fund and the Venture Program

The Common Fund Moves the NIH Mission Forward – Faster

Supporting bold scientific programs that **catalyze discovery** across all biomedical and behavioral research

Advances areas of biomedical and behavioral research important to the missions of multiple NIH Institutes and Centers

Spurs subsequent biomedical advances that otherwise would not be possible without an initial strategic investment



Features of Common Fund Programs and How They Catalyze Biomedical Discovery

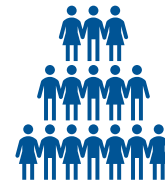
Making substantial investments in time-limited, goal-driven programs that significantly change the trajectory of biomedical research.



Accelerate
emerging
science



Remove
research
roadblocks



Enhance the
research
workforce



Support high-risk,
high-reward
science

Common Fund Science and Management are Collaborative



Scientists from diverse disciplines provide input as we plan new programs.



Researchers participate in interdisciplinary consortia to tackle shared goals.



Leadership and staff from Institutes, Centers, and the Office of the Director work together to design funding opportunities and oversee the projects.

Common Fund Venture Program

“Amazing things with modest funding”

The Venture Program will make Common Fund support available for short-term initiatives that embrace scientific risk

Prioritized by ICO Director Venture Board, with final approval by NIH Director

Criteria:

- Emphasis on **innovation** and **speed**
- Projects should have **potential for major impact** and **embrace scientific risk**

Features of Venture Space projects:

- Brief funding, no more than **3 years**
- Clearly defined goals with **go/no-go milestones**
- **Flexible approach** to funding mechanisms and project timelines
- **Smaller scale** cross-cutting initiatives
- **Nimble, streamlined** management

Overview of the SysBio ROA

New Venture Initiative: A Systems Biology Data Model

Background and Goals:

Many NIH-supported multi-omic analyses in humans:

- Multiple tissues with deep phenotyping
- Rich datasets siloed in different platforms

Urgent need to enable integrated view of human disease

- molecular, phenotypic, clinical, and outcomes data

NIH Accelerating Medicines Partnership (AMP)

- Many ICs participate
- Robust but independent datasets for different diseases and tissues
- Starting point / Test case for an ecosystem for integrated analyses

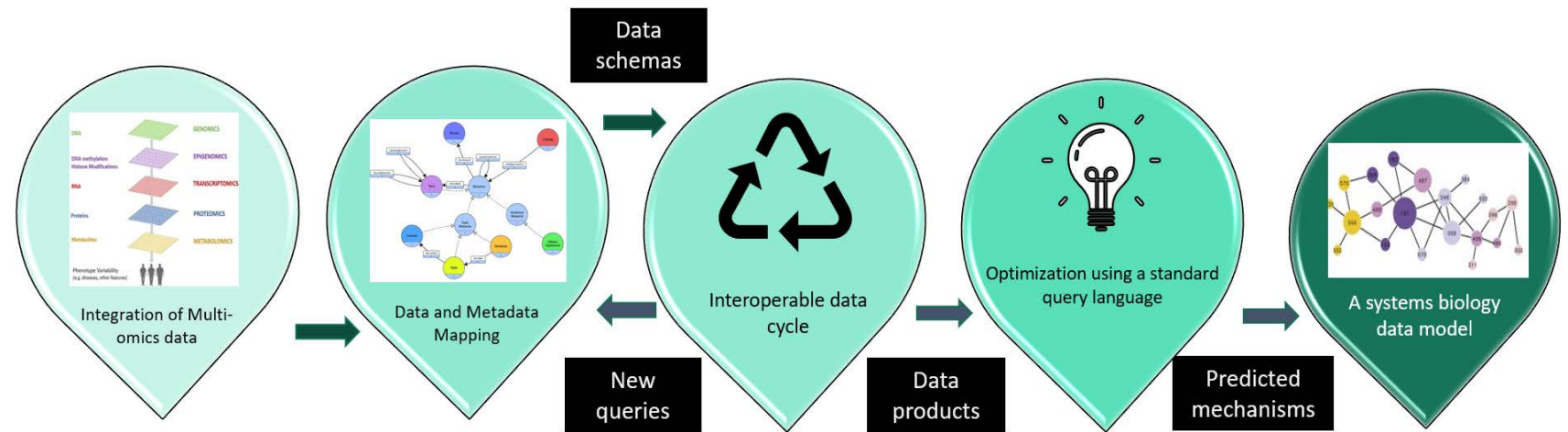
This Venture Space initiative would develop a systems biology data ecosystem, across separate data platforms through a single portal.

- Explore mechanistic hypotheses across different tissues
- Identify shared mechanisms
- Link to patient phenotypes in chronic diseases

New Venture Initiative: A Systems Biology Data Model

Anticipated Work Products:

- Centralized system architecture for federated data sharing
- Computational Framework and query language for Systems Biology
- A Proof of Concept (POC) study
- Effective modes of visualization



Impact:

- Robust data portal and computational resources to query across data ecosystem
- Establish a foundation to drive:
 - Biological insights
 - More precise and personalized patient care

Other Transactions

- **Not a grant, cooperative agreement, or a contract**
- OTs allow the **nimble addition or subtraction** of expertise, tools, technologies, and partnerships
- Many Public Policies apply to OT, though not FAR or NIH Grants Policy
- Objective Review of OTs **do not follow traditional NIH review process**. The OT Team develops the criteria and composition of the review which is designed to ensure integrity, fairness and transparency.
- Award **funding is different** (e.g., variable segment lengths, no future commitment, can be terminated or extended by NIH, etc.)
- Changes in project and budget are different (e.g., **NIH can propose changes**, threshold for prior approval, etc.)

OTA-24-008

https://commonfund.nih.gov/sites/default/files/Research-Opportunity-Announcement-OTA-24-008-SysBio-updated-20240311_508.pdf

The purpose of this ROA is to establish a **Systems Biology Data Platform (SysBio)** that leverages data from **multiple Accelerating Medicines Partnership (AMP) programs**.

- Will provide a single access point for querying data across tissues and conditions studied by AMP.
- Will enable broad use of the datasets and knowledge generated by AMP.
- Will consist, at a minimum, of a search portal and a linked cloud-based workspace.

Function 1: Project Management and Coordination

- Track milestones, ensure timely deliverables, facilitate timely submission of progress reports and other periodic materials.
- Organize SysBio meetings and develop a documents and approvals tracking system.
- Support external communications with the scientific community and industry partners.
- Develop a plan to account for potential discontinuation of support or transition of the SysBio platform support to a new source.

Function 2: Data Security

- **Provide a consistent process for user registration and for accessing controlled data.**
- **Streamline the controlled data access request processing to the greatest extent possible without compromising vigilance.**
- **Ensure that the information system hosting SysBio is protected from unauthorized access (NIST SP 800-53 standards).**
- **Ensure that SysBio or AMP data are not provided to a generative AI tool that is not developed and maintained for the exclusive purpose of serving SysBio.**

Function 3: Data Harmonization

- **Develop an inventory of key AMP datasets and the associated metadata.**
- **Develop a solution that enables queries across AMP datasets.**
- **Develop tools to automate mapping between variables in different AMP datasets.**
- **Produce a set of harmonized data that allows querying by specific gene, molecule, or cell type/disease state.**

Function 4: Establish the SysBio Platform

- Deploy a portal that allows users to search the harmonized data by querying for specific genes, molecules, or cells.
- Develop and deploy a cloud-based workspace that allows users to work with AMP data identified through the portal.
- Develop a search tool that allows selection of datasets (derived or primary) based on a metadata query by the user.
- Identify complementary datasets and tools from non-AMP sources (e.g., the Common Fund Data Ecosystem), and enable their use.

Plan for Enhancing Diverse Perspectives (PEDP)

The application must include a Plan for Enhancing Diverse Perspectives (PEDP). Diverse perspectives can refer to people who do the research and the places where the research is done, as well as to who participates in the research as a part of the study population. Must include:

- Description of defined activities and actionable strategies for the inclusion of diverse perspectives in the project.
- Description of how the PEDP will bring advantages or unique capabilities to the project.
- Milestones for the evaluation of PEDP activity progress and success.
- Anticipated timeline of proposed PEDP activities.

Please note – the PEDP is a part of the criteria that will be scored during the Objective Review

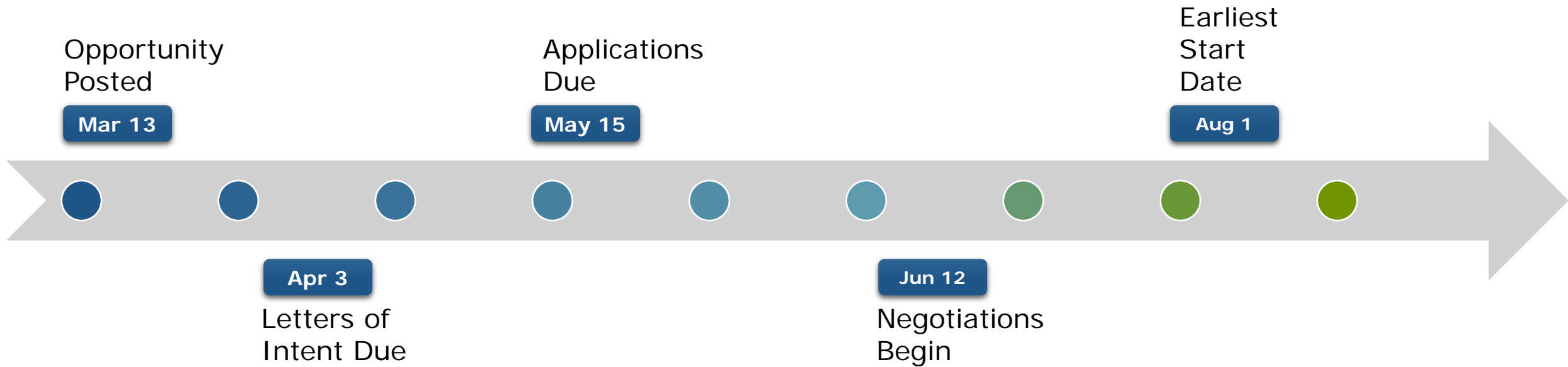
Data Sharing and Management

- All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.
 - <https://sharing.nih.gov/data-management-and-sharing-policy>
- Must develop and maintain good documentation and manuals/training materials.
- Scientific data should be made accessible as soon as possible, and no later than the time of an associated publication or the end of the performance period of the extramural award that generated the data.

PI Eligibility and Minimum Effort Requirements

- More than one individual may be named as PI; one individual must be identified as the contact PI.
- The contact PI must be employed by or affiliated with the applicant organization.
- If a multiple Principal Investigator (MPI) application is submitted, an MPI leadership plan is required as part of the overall Leadership Plan.
- NIH expects the proposed project to include an individual that will serve as the Program Manager/Director (PM/PD) for the project.
- PM/PD should commit at least 50% level of effort to the project.

Timeline Overview



Letter of Intent (LOI)

- LOIs are **not** required to be eligible to submit a full proposal, however, submitting an LOI is **strongly encouraged**.
- Due Date: **April 3, 2024**
- NIH will use the LOI to assess eligibility of the applicant organization and to identify conflicts of interest for potential reviewers
- NIH will **not** provide feedback about the scientific and technical content of the LOI, **nor** make recommendations for improvements.

Due date: May 15, 2024

- Applications will have multiple components as listed in the ROA
- If applicable, page limits for components are stated in the ROA
- Title the components the same way they are named in the ROA
- **Due by 5 pm local time of applicant organization. Late applications will not be accepted**
- Applications must be submitted electronically through ASSIST **and** as a single collated PDF file anthony.kirilusha@nih.gov and sysbio@od.nih.gov

For additional information:

Visit the FAQ

page: <https://commonfund.nih.gov/venture/sysbio/faqs>

Contact the Program Team: sysbio@od.nih.gov



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Questions and Answers

Thanks for attending



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